

B¹
binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product from the donor mammal, wherein the blood or blood product determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to the recipient mammal.

Sub B²
2. (Once amended) The method of claim 1, wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal.

B³
7. (Twice amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in donor blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria is useful for transfer to the recipient mammal.

Sub B⁴
8. (Twice amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in donor blood product from a donor mammal for transfer to a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product and no binding indicates the absence

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of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacteria is useful for transfer to the recipient mammal.

Sub B1
B4
14. (Twice amended) A method for screening for the presence of a clinically relevant amount of bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to the recipient mammal.

Sub B1 B5
15. (Once Amended) The method of claim 14, wherein the donor tissue determined to have an absence of a clinically relevant amount of bacteria is transferred to the second mammal.

Sub B1
B6
17. (Twice Amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria is useful for transfer to the recipient mammal.

18. (Twice Amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in a donor tissue from a donor mammal for transfer to a

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recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of binding agents to the Gram-negative bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor tissue, and wherein the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacterial is useful for transfer to the recipient mammal.

Sub C7
23. (New) The method of any of claims 1, 7, 14, and 17, wherein the set of binding agents that selectively bind Gram-positive bacterial antigens is selected from the group consisting of an antibody, [an antigen-binding fragment thereof, a small molecule, an antibiotic, mannose binding protein (MBP), Toll-Like Receptor 2 (TLR-2), and histatins.

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24. (New) The method of any of claims 1, 8, 14, and 18, wherein the set of binding agents that selectively bind Gram-negative bacterial antigens is selected from the group consisting of an antibody, [an antigen-binding fragment thereof, a *Limulus* anti-lipopolysaccharide factor (LALF), a lipopolysaccharide binding protein (LBP), a bactericidal/permeability-increasing protein (BPI), a small molecule, and an antibiotic, wherein the antibiotic is not vancomycin.] 32

Sub C7
25. (New) The method of claim 24, wherein the antibiotic is polymixin or bacitracin.

26. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the set of binding agents are detectably labeled with a reporter molecule.

Sub B7
27. (New) The method of claim 26, wherein said reporter molecule is selected from the group consisting of a molecule with enzymatic activity, a radio-labeled molecule, a fusion molecule, a fluorogenic molecule, a metal sol, a particle, a chromatic molecule, [or a molecule that is specifically bound by a secondary agent.]

28. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than 1×10^7 colony forming units per milliliter (CFU/ml) of blood or blood product.

29. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than 1×10^6 CFU/ml of blood or blood product.

Sub D
30. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than 1×10^5 CFU/ml of blood or blood product.

31. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than 1×10^4 CFU/ml of blood or blood product.

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32. (New) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than 1×10^3 CFU/ml of blood or blood product.

✓ 33. (New) The method of claim 27, wherein the enzymatic molecule is selected from the group consisting of horseradish peroxidase, alkaline phosphatase, and β -galactosidase.

34. (New) The method of claim 26, wherein said reporter molecule is bound to the binding agent by intermolecular association

The amendments to the claims presented above incorporate changes as indicated by the marked-up versions below. For the examiner's convenience, a copy of all of the pending claims are provided, whether amended or not.

1. (Amended) A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer to recipient mammal comprising: contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting ~~determining~~ binding of the set of binding agents to the sample,

wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product from the donor mammal, wherein the blood or blood product determined to have an absence of a clinically relevant amount of bacteria is as useful for transfer to the recipient mammal.

2. (Amended) The method of claim 1, wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is useful for transferred to a ~~the~~ recipient mammal.

3. (Reiterated) The method of claim 1, wherein the donor blood or blood product is selected from the group consisting of whole blood, leukocytes, hematopoietic stem cells, platelets, red blood cells, plasma, and serum.

4. (Reiterated) The method of claim 1, wherein the binding agents that specifically bind to the Gram-negative bacterial antigen specifically bind to the lipopolysaccharide structure of the Gram-negative bacteria.

5. (Reiterated) The method of claim 1, wherein the binding agents that specifically bind to the Gram-positive bacterial antigen specifically bind to the lipoteichoic acid structure of the Gram-positive bacteria.

6. (Reiterated) The method of claim 1, wherein the set of binding agents is immobilized on a solid-phase support.

7. (Amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in donor blood product from a donor mammal for transfer to a recipient mammal comprising: contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, detecting ~~determining~~ binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product and no binding indicates the absence of a

clinically relevant amount of Gram-positive bacteria in the donor blood or blood product, and wherein identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria is as-useful for transfer to the recipient mammal.

8. (Amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in donor blood product from a donor mammal for transfer to a recipient mammal comprising: contacting a sample of the donor blood or blood product with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, detecting ~~determining~~ binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product, and wherein identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacteria is as-useful for transfer to the recipient mammal.

14. (Amended) A method for screening for the presence of a clinically relevant amount of bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting ~~determining~~ binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of bacteria in the donor tissue, and wherein identifying the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is as-useful for transfer to the recipient mammal.

15. (Amended) The method of claim 14, wherein the donor tissue determined to have an absence of a clinically relevant amount of bacteria is transferred to the second mammal.

16. (Reiterated) The method of claim 14, wherein the donor tissue is selected from the group consisting of lung, heart, liver, skin, kidney, pancreas, spleen, and bone marrow.

17. (Amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, ~~detecting determining~~ binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor tissue, and ~~wherein identifying~~ the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria is as-useful for transfer to the recipient mammal.

18. (Amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding agents, wherein the set of binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, ~~detecting determining~~ binding of the set of binding agents to the Gram-negative bacterial antigen ~~and the Gram-positive bacterial antigen~~ in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor tissue, and ~~wherein identifying~~ the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacterial is as-useful for transfer to the recipient mammal.

REMARKS

Claims 1-8 and 14-39 are pending in this application. Applicants respectfully request reconsideration in view of the following remarks.